MAR 2 2 2005

510(k) Summary of Safety & Effectiveness

K043225

Submitter

Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, FL 33815

Contact

Heather Crawford, RAC
Director of Regulatory Affairs
863-683-8680 [voice]
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Date

November 20, 2004

Device

- Trade Name: Vanguard Reprocessed Ultrasonic Scalpel
- Common Name: Ultrasonic Surgical Instrument
- 21 CFR Section: Unclassified
- Product Code: NLQ – Scalpel, Ultrasonic, Reprocessed – Class II

Predicate Devices

- Trade Names:
  - Ethicon Endo-Surgery UltraCision® Harmonic Scalpel®
- 510(k) numbers:
  - K925699: Ultracision, Inc., Harmonic Scalpel Laparosonic Clamp Coagulator
  - K980099: Ethicon Endo-Surgery, Inc., UltraCision LaparoSonic Coagulating Shears LCS-5
  - K993054: Ethicon Endo-Surgery, Inc., UltraCision Harmonic Scalpel LCS and CS Curved Shears

Indications for Use

The Reprocessed Ultrasonic Scalpel is intended for use during minimally invasive laparoscopic and open surgical procedures where coagulation and incision of soft tissue is required.

Contra-indications

This instrument is not intended for contraceptive tubal ligation or for bone excision.

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510(k) Summary of Safety & Effectiveness, Continued

Device Description

The Reprocessed Ultrasonic Scalpels are hand held instruments which may be used to cut and coagulate tissue when connected to a compatible ultrasonic handpiece and generator. Scalpels are 5mm in diameter with functional lengths of 14 to 36cm. The instrument jaws are opened and closed using proximal ring handles, available with a pistol or scissor grip style. The instrument tip and shaft can be rotated 360° in either direction using a knob on the handle. Scalpels are available with various blade configurations: curved, blunt, and knife down.

The proximal handle is designed for attachment to a compatible handpiece and microprocessor controller. Electrical outputs from the controller are converted by an ultrasonic transducer within the handpiece to mechanical vibrations that are transmitted through the instrument shaft to the distal scalpel blade.

Vanguard receives previously used Ultrasonic Scalpels from healthcare facilities; cleans, inspects, tests, packages, labels, and sterilizes the devices; and returns them to a healthcare facility for subsequent use.

Technological Characteristics

The Vanguard Reprocessed Ultrasonic Scalpels are essentially identical to the currently marketed Original Equipment Manufacturer (OEM) devices. No changes are made to the device materials or specifications and the reprocessed Ultrasonic Scalpels possess identical technological characteristics.

Test Data

Cleaning, sterilization, and packaging validations, and performance and biocompatibility testing demonstrate that the reprocessed devices perform as intended and are safe and effective.

Conclusion

Based upon the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that Vanguard Reprocessed Ultrasonic Scalpels are substantially equivalent to their predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2005

Ms. Heather Crawford, RAC
Director of Regulatory Affairs
Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, Florida 33815

Re: K043225
Trade/Device Name: Vanguard Reprocessed Ultrasonic Scalpel
Regulatory Class: Unclassified
Product Code: NLQ
Dated: February 17, 2005
Received: February 18, 2005

Dear Ms. Crawford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Vanguard Reprocessed Ultrasonic Scalpel

Indications for Use:

Reprocessed Ultrasonic Scalpel is intended for use during minimally invasive laparoscopic and open surgical procedures where coagulation and incision of soft tissue is required.

Prescription Use__X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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General, Restorative
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